REMARKS

Claims 1-74 are pending in the application. Claims 31-45 have been withdrawn. Claims 56 and 57 have been rejoined by the Examiner as stated in the November 15, 2005, Office Action.

I. Claim Rejection-35 USC § 112, first paragraph

Enablement

Claims 11,13 and 16-18 stand rejected under 35 USC §112, first paragraph, for failure of the specification to comply with the enablement requirement. The Examiner states that the specification does not provide a repeatable method for obtaining the constructs rPIV3-2TM, rPIV3-2TMcp45, rPIV3-2CT and rPIV3-2CTcp45. Applicants respectfully disagree.

The constructs rPIV3-2TM and rPIV3-CT are derived from the genomes of HPIV2 and HPIV3, (see, e.g. Example 6 and Figures 7-8). HPIV2 and HPIV3 viruses are available from the American Type Culture Collection, (ATCC) in Manassas, VA (VR-92™, VR-93, respectively). Cloning of the genomes of these viruses into a form recoverable from cDNA was described in Applicants' prior applications and papers (e.g. Durbin et al. (1996)).

rPIV3-2TM can be described as containing coding regions from the transmembrane domains of HN and F genes from HPIV2 in a HPIV3 background. Similarly, the rPIV3-CT construct contains coding regions from both the transmembrane domains and ectodomains of HN and F HPIV2 genes in a HPIV3 background. The full-length antigenomic cDNAs bearing the rPIV3-2TM construct and the rPIV3-2CT construct, are depicted in Figure 9 and listed as SEQ ID NO: 40 and SEQ ID 41, respectively, in the instant specification. As depicted and described in the above referenced Figures and Example, the 12 cp45 mutations were introduced into the PIV3 portions of the rPIV3-2TM and rPIV3-2CT constructs to obtain the derivatives rPIV3-2TMcp45 and rPIV3-2CTcp45. Because the specification describes the invention in such terms that one skilled in the art can make and use the claimed invention from readily available starting

materials, claims 11,13 and 16-18 are enabled. Applicants respectfully request that the rejection be reconsidered and withdrawn.

Written Description

Claims 26 and 71 stand rejected under 35 USC §112, first paragraph, for alleged lack of written description support. Claims 26 and 71 are drawn to a virus or nucleic acid comprising a genome or nucleic acid, respectively, that includes a mutation encoding a substitution of amino acid 456 of the L protein by another amino acid. The Examiner contends that because the specification only describes a mutation where the amino acid at position 456 of PIV3 is changed to leucine, and the claims encompass a substitution of any of the 20 amino acids, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of polypeptides. Applicants strongly disagree.

Recently, the Federal Circuit stated that a sequence need not appear in a patent specification to support a DNA-based invention provided that the state of the scientific knowledge at the time the application was filed includes such structural information. *Capon et al. v. Eshhar et al. v. Dudas*, 76 USPQ2d 1098 (Fed. Cir. 2005).

In the instant case, a skilled artisan would be fully aware of the structure of the genus of polypeptides claimed. The skilled artisan would merely have to replace the nucleotide sequence encoding an amino acid at the specified location recited in the claims with any of the well-known nucleotide sequences that encode the desired amino acid. Therefore, the present specification complies with the written description requirement. Applicants respectfully request the instant rejection be withdrawn.

II. Claim Rejections – 35 USC §102

Claims 1-10, 12, 19-23, 25, 28-30, 46-49, 53-59, 65, 66 and 77-74 stand rejected under 35 USC §102(e) as assertedly being anticipated by US Patent No. 5,869,036 to Belshe et al. ("Belshe"). Applicants respectfully traverse.

Belshe discloses the cp45 genome in schematic form and provides a summary description of hybrids thereof. Belshe's hybrid genomes are derived by replacing the regions encoding the cp45 glycoproteins with cDNA copies of corresponding genes of a "target" virus. (See Col 9, lines 54-59 and Col. 10 lines 19-22).

In contrast, independent claims 1, 53, 56, 58, 59 and 66 all recite the element of a PIV genome encoding a "chimeric glycoprotein." That is, one or more segments of a nucleic acid(s) encoding a portion of a glycoprotein from one type of PIV genome is replaced by a segment(s)

of a nucleic acid encoding a portion of a glycoprotein from another PIV genome. For example, the nucleic acids encoding the PIV3 ectodomain and transmembrane domains of an HN or F gene can be replaced with the nucleic acids encoding the ectodomain and transmembrane domains from the PIV2 HN or F gene, leaving the HN or F PIV3 cytoplasmic domains undisturbed.

Although the Examiner states "the claims do not recite limitations that distinguish over Belshe with regard to joining segments together", the term "chimeric glycoprotein" as recited in the instant claims is a feature that distinguishes the claimed invention over Belshe. Belshe discloses replacing the entire HN or F gene from PIV3 with the entirety of an HN or F gene from a different viral genome without teaching or suggesting inserting a chimeric glycoprotein, e.g. a single HN gene comprised of coding sequences from two different PIV genomes, into the background PIV genome.

Because a claim is anticipated only if each and every element as set forth in the claim is disclosed in a reference, the Belshe reference does not anticipate the claims. For the above reasons, independent claims 1, 53, 56, 58, 59 and 66, and claims dependent thereon, are not anticipated by Belshe.

Rejection for non-statutory double-patenting

The Examiner presents a number of provisional obviousness-type double patenting rejections. Applicants request that these issues should be held in abeyance since prosecution is

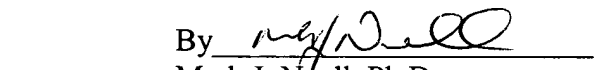
continuing in both cases and the issue may be resolved by amendments in the various applications. See MPEP 804. If necessary, Applicants will file a Terminal Disclaimer following the procedure outlined in the above-mentioned section of the MPEP.

The present application well-describes and claims patentable subject matter. The favorable action of allowance of the pending claims and passage of the application to issue is respectfully requested.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Mark J. Nuell (Reg. No. 36,623) at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

Dated: February 15, 2006

Respectfully submitted,

By 

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